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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/637,205	08/08/2003	Terrence S. McGrath	6619-85-1CON	4081

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AKERMAN SENTERFITT
P.O. BOX 3188
WEST PALM BEACH, FL 33402-3188

EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
07/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/637,205	MCGRATH ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,10,11 and 13-21* is/are pending in the application.

4a) Of the above claim(s) *19, 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,10,11 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt of remarks and amendments to the claims filed 5/16/07 is acknowledged.

STATUS OF CLAIMS:

- Claims 1, 2, 4-7, 10, 11, 13-21 are pending in the application.
- Claims 20 and 21 were withdrawn from consideration.

STATUS OF THE OFFICE ACTION: Final

CLAIM REJECTIONS

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. In view of the current claim amendment the rejection of claim 10 for insufficient antecedent basis is withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-7, 10, 11, 13-19 remain rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al. US 5,766,490 (hereinafter Taylor).

Taylor teaches a process to enable the production of water highly enriched with oxygen with a higher concentration of dissolved oxygen and with longer retention of the dissolved oxygen in the water (col. 2, lines 41+). The superoxygenated water of Taylor can be advantageously employed in, for example, increasing the oxygen content of blood and tissues; oxygenation of wounds to increase the rate of healing and to reduce infections; oxygenated organ transplant storage media; tumor oxygenation for radiation therapy and chemotherapy; lung bypass by oxygenated liquids in case of pulmonary deficiencies; carbon monoxide poisoning; mouthwashes, dentrifices; topical, including cosmetic, treatment media; contact lens treating solutions; and cell level therapeutic applications (col. 5, lines 26+). Taylor discloses that oxygen is distributed in the water as bubbles and also as some amount of oxygen dissolved in the water (col. 7, lines 18+). Claim 1 recites the limitation " for a time sufficient to increase the subepithelial partial oxygen pressure from about 30% to about 12)% above baseline pO_2 ". The time is considered inherent since the application is the same way "topical" and applied to the same lesions "wounds" and for the same reason which is enhancing healing and because the pharmaceutical vehicle comprising the oxygen would inherently be left on the lesion for a suitable time that will give oxygen bubbles the chance to work sufficiently on the tissue.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a). Claims 1, 2, 4-7, 10, 11, and 13-19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. US 5,766,490 in view of Ladin et al US 5, 792, 090 (hereinafter Ladin) and further in view of Kolta et al US 6, 139, 876 (hereinafter Kolta).

Taylor has been discussed above.

Taylor does not specifically disclose the oxygen bubble size.

Ladin discloses a method of healing of surface wounds, including burns, which is facilitated by increasing the wound oxygen tension through the application of an oxygen-generating wound dressing which renewably and non-sustainingly chemically generates oxygen. The wound dressing contains an oxygen permeable membrane and an oxygen supply solution. Because the oxygen chemically produced by the subject invention may include both gaseous oxygen as well as dissolved oxygen, the membrane pore sizes of from 0.01 to 10 micron, preferably 0.1 to 1.0 microns are preferred to limit the oxygen passage (col. 5, lines 16+).

The two references did not disclose a method to treat anaerobic bacterial infections.

Kolta discloses a gelatin with increased oxygen content for pharmaceutical, cosmetic and/or veterinary use. The gelatin comprises a gelling agent and a solvent, furthermore oxygen in a substantially even distribution with a pressure exceeding normal atmospheric pressure (abstract). Kolta teaches that gelatin and the oxygen encapsulated therein will have special synergetic effects. The intensive presence of oxygen will prevent proliferation of anaerobe bacteria which otherwise would rapidly multiply in the gelatin (col. 2 line 12+)

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to expand the teaching of Taylor by realizing a fine size of the oxygen bubbles because the size of the bubble relate inversely with the penetration of the tissue and also to ensure the effect of the method on the anaerobic bacteria because Kolta discloses that the presence of oxygen ensures the prevention of proliferation of anaerobic bacteria. The expected result would be a method for increasing skin oxygenation by applying a composition of high oxygen concentration to a wound, or burn in a topical application or a bath.

RESPONSE TO ARGUMENTS

Applicant's arguments filed 5/16/07 have been fully considered but are not persuasive.

Rejection under 35 U.S.C. §102

Applicant argues that:

- Taylor et al. does not teach all the limitations of claim 1 as amended and dependent claims 2, 4-7, 10, 11 and 13-19. The claim require a method of increasing tissue oxygenation in mammals that involves directly applying a composition to skin or

mucous membranes that increases the partial oxygen pressure at least about 2 mm beneath the tissue surface from about 30% to about 120% above baseline pO2".

To respond: the amendments to the claims does not exclude Taylor et al. Applicant's invention is limited to a method on one step which is applying a superoxygented composition of oxygen microbubbles to skin or mucous membrane. Taylor et al. discloses a process to enable the production of water highly enriched with oxygen with a higher concentration of dissolved oxygen and with longer retention of the dissolved oxygen in the water (col. 2, lines 41+). Note that the dissolved oxygen to be released has to turn into the gas phase and consequently bubbles. The composition can be advantageously employed in increasing the oxygen content of blood and tissues; oxygenation of wounds to increase the rate of healing and to reduce infections; oxygenated organ transplant storage media, mouthwashes, and cell level therapeutic applications (col. 5, lines 26+), note also that the cell level therapeutic should reach to some cell level in the depth as required by claim 1. Taylor discloses that oxygen is distributed in the water as bubbles and also as some amount of oxygen dissolved in the water (col. 7, lines 18+). Increasing the partial oxygen pressure at least about 2 mm beneath the tissue surface from about 30% to about 120% above baseline pO2 would be an inherent property of the same composition disclosed by Taylor and which is disclosed as used for skin wounds and implantable organs.

- As another example Taylor t al. does not teach "microbubbles consisting essentially of oxygen in a pharmaceutically acceptable vehicle."

To respond: Taylor et al. teaches a process to enable the production of water highly enriched with oxygen which can be advantageously used in increasing the oxygenation of wounds to increase the rate of healing. Taylor also discloses that oxygen is distributed in the water as bubbles and some amount of oxygen dissolved in the water (col. 7, lines 18+)

Rejection under 35 U.S.C. §103

Applicant argues that:

- None of Taylor et al., Ladin, and Kolta teach or suggest the limitation of "to increase the partial oxygen pressure at least about 2mm beneath the tissue surface from about 30% to 120% above baseline pO2" Applicants note that Ladin, in contrast, discloses measuring the pressure of oxygen on a probe inserted into the perichondrium that covers the cartilage of a rabbit's ear after the skin and subcutaneous tissue was removed. Physically removing the skin to proved oxygen to the perichondrium, which is normally below the skin, does not teach an increase in partial oxygen pressure at least two millimeters beneath the surface of a tissue.

To respond: example 4, which Applicant cites is done by making full thickness wound was created on the inner surface of the rabbit's ear. Skin and subcutaneous tissue were removed down to the perichondrium then applying the dressing to increase the oxygen pressure to the depth of the wound. Inserting the probe –reports that there is a depth to through- is to measure the oxygen pressure and the results shows an increase in oxygen from about 100 mm Hg to a relatively constant elevated level of c.a. 138 mm

Hg after only 8 minutes. Accordingly, it is clear that the dressing is used topically while the increase in the oxygen depth reaches the perichondrium.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim 7/21/07

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER